UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ELIZABETH TANGNEY, Plaintiff, v. SYLVIA MATHEWS BURWELL, SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	)	CIVIL ACTION NO. 14-14149-WGY

YOUNG, D.J. May 10, 2016

MEMORANDUM & ORDER

I. INTRODUCTION

Elizabeth Tangney is very sick, suffering from severe nausea, vomiting, and abdominal pain. For several years, a team of physicians struggled to find something that would alleviate her symptoms. They finally succeeded in 2011 when they administered Dronabinol. Her insurance at the time covered it. When Tangney switched to Medicare in May 2014, however, its Part D program denied coverage on the ground that the off-label use prescribed to Tangney was not "supported by one or more citations in [approved] . . . compendia[.]" 42 U.S.C. § 1396r-

8(k)(6). An Administrative Law Judge ("hearing officer")[1] disagreed with this initial determination and granted coverage, but the Medicare Appeals Council (the "Council") then reversed. As a result, Tangney is again without coverage for her Dronabinol prescription.

The parties agree[2] that Tangney's use of Dronabinol has been successful in treating her symptoms. Compare Mem. Law. Supp. Def.'s Mot. Order Affirming Dec. Sec. ("Def.'s Mem.") 12, ECF No. 21, with Pl.'s Mem. Supp. Mot. Reverse or Remand Dec. Sec. ("Pl.'s Mem.") 1, ECF No. 18. They also agree on the regulatory requirements for coverage. Compare Def.'s Mem. 8, with Pl.'s Mem. 10. Based on the plain language of the statute and the undisputed facts in this case, Tangey's prescription must be covered by Part D; accordingly, the Court grants her motion to reverse the Council's decision.

A. Undisputed Facts

The parties agree on the underlying facts. Compare Def.'s Mem. 2-3 with Pl.'s Mem. 4. This section briefly summarizes the pertinent ones, drawing from the findings of the hearing officer as adopted by the Council.

---

[1] See Vega v. Colvin, No. CV 14-13900-WGY, 2016 WL 865221, at *1 (D. Mass. Mar. 2, 2016) (explaining the Court's use of the term "hearing officer").

[2] The parties' briefing here reflects conscientious lawyering. Tangney and the Secretary agree on many things, focusing this Court's review on what is truly in dispute.

In 2004, Tangney underwent surgery "to correct a partial intestinal obstruction and an abdominal wall hernia." Administrative R. ("Admin. R.") 0008, ECF No. 14-1.[3] After this surgery, she developed increasingly severe "abdominal pain, nausea, and vomiting." Id. at 0009. Her surgeon and gastroenterologist prescribed her various anti-nausea treatments and medications, but "none of them worked." Id. In August 2011, her doctors prescribed her Dronabinol, which significantly relieved her nausea and vomiting. Id. Her insurer at the time covered the treatment, and for three years thereafter she continued to take Dronabinol and her symptoms were lessened. See id.

Then, in May 2014, Tangney enrolled in Medicare Part D, which declined coverage for Dronabinol. See id. After Tangney ran out of Dronabinol, she became dehydrated, lost weight, and was hospitalized for three weeks. See id.

B. Procedural History

Tangney requested reconsideration of the initial determination declining coverage, which request was denied. Admin. R. 0009-0010. She appealed this determination to a hearing officer. Id. at 0125. On June 26, 2014, the hearing

[3] The record of the administrative proceedings covers docket entries 14-1 through 14-5. Since this record is consecutively numbered throughought the different docket entries, the Court cites to the page number, omitting the ECF number from all future citations.

officer found that Tangney's Dronabinol "was prescribed for a 'medically accepted indication' . . . based on support in the compendia[,]" and ruled that her "Medicare Part D Plan must cover Dronabinol[.]" Id. at 0132-0133. The next month, Maximus Federal Services, a contractor tasked with reviewing Medicare determinations, petitioned the Council for review of the June decision. Id. at 0007. On review, the Council noted that "[Tangney's] physician and attorney, and the [hearing officer], have presented compelling arguments that the enrollee's use of Dronabinol is medically supported by testimony and the record." See id. at 0023. In its September 2014 decision, the Council nonetheless reversed, concluding that Tangney's use of Dronabinol was not covered. See id.

Tangney filed a complaint in this Court in November 2014. Compl., ECF No. 1. Before the Court now are the parties' cross-motions: Tangney's asking for either reversal or a remand to the Secretary, Pl.'s Mot. Reverse or Remand Decision Sec'y, ECF No. 17; and the Secretary's requesting an affirmance, Def.'s Mot. Order Affirming Decision Sec'y, ECF No. 20. The issues have been thoroughly briefed. See Pl.'s Mem.; Def.'s Mem.; Pl.'s Reply Mem. Opp. Def.'s Mot. Order Affirming Dec. Sec. ("Pl.'s Reply"), ECF No. 22.

II. BACKGROUND

The Court first briefly sketches the statutory framework surrounding Tangney's claim before discussing the underlying compendium entry at issue.

A. Medicare Part D Prescription Drug Coverage

Medicare Part D supplements Medicare[4] by partially covering certain prescription drugs. First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 48 (1st Cir. 2007) (citing Pub. L. No. 173, Tit. I (2003) (Part D); 42 U.S.C. § 1395u–102(b)). "[A]ny use of a [prescription] drug for a medically accepted indication" is covered. 42 U.S.C. §§ 1395w-102(e)(1) (emphasis supplied). "'[M]edically accepted indication' means any use . . . approved [by the FDA] or the use of which is supported by one or more citations included or approved for inclusion in any of the [listed] compendia[.]" 42 U.S.C. § 1396r-8(k)(6).

As mentioned at the outset, the parties, by their briefing, have narrowed the Court's inquiry. They agree that Tangney's use is not one approved by the FDA. Compare Def.'s Mem. 3, with Pl.'s Mem. 10. They both assert that the Drugdex Information System ("Drugdex") is among the listed compendia,[5] 42 U.S.C. §

[4] For a discussion of Medicare generally, see, for example, First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 48 (1st Cir. 2007).

[5] The Seventh Circuit has described the compendia as "large reference books that contain a variety of information about the prescription pharmaceuticals currently available on the American market -- everything from their chemical makeup to potential

1396r-8(g)(B)(i)(III), and is the relevant one for the Court's analysis. Compare Def.'s Mem. 8, with Pl.'s Mem. 10. Neither party suggests that there is a relevant citation "approved for inclusion" in Drugdex. In other words, whether this use of Dronabinol is "supported by one or more citations" in Drugdex, the parties agree, is the crucial inquiry. See Def.'s Mem. 8 (citing 42 U.S.C. § 1296r-8(g)(1)(B)(i)); Pl.'s Reply 2.

B. The Compendium and Citation at Issue

Before beginning its analysis, the Court summarizes both the relevant Drugdex entry and the study it cites. Both of these are relevant to the issue of whether Tangney's use is "supported by" a citation in Drugdex.[6]

---

side-effects to the age ranges of patients the drugs have been tested on." United States v. King-Vassel, 728 F.3d 707, 715-16 (7th Cir. 2013) (citing Edmonds v. Levine, 417 F.Supp.2d 1323, 1332–33 (S.D. Fla. 2006)). It noted that the compendia "seem to be intended primarily for an audience of health care professionals, but again, were specifically incorporated by Congress into the statutory standard for a "'medically accepted indication.'" Id. at 716 (internal citations omitted).

[6] Tangney argued, in her first memorandum submitted to this Court, that the "citation" in the statutory phrase refers not to the underlying study to which the Drugdex entry provides a direct citation, but to the Drugdex entry itself. Pl.'s Mem. 18 ("The plain meaning of the statutory language 'supported by a citation' is [not] limited to the medical literature underlying an entry in Drugdex[.]"). She then, however, appeared to concede that the underlying study is relevant to the Court's analysis. See Pl.'s Reply 4 ("[Tangney] agrees that for a use to be supported by citation it must be 'consistent' with the compendium citation, but [Tangney] does not agree that this requires an identical diagnosis to the one or ones in the underlying study when the purpose of the drug is to treat an

1. Drugdex Entry

Drugdex is a "listing of drugs that includes evidence regarding the drug's effectiveness, clinical indications, and proper dosing." Lindsey Gabrielsen, Bias at the Gate?: The Pharmaceutical Industry's Influence on the Federally Approved Drug Compendia, 40 Am. J.L. & Med. 141, 141 (2014) (internal citation omitted). The Drugdex entry at issue is for Dronabinol. See Admin. R. 0168. Unfortunately, as has been noted by another court, Drugdex does not have "a section entitled 'Uses Supported by Citation' (i.e., tracking the language of the statute)," Edmonds v. Levine, 417 F.Supp.2d 1323, 1332-33 (S.D. Fla. 2006). The parties thus focus on the section of the Dronabinol entry entitled "Clinical Applications[.]" Admin. R. 0179. This section lists eight "Therapeutic Uses,"[7] the relevant one being: "Nausea and

---

identical symptom."). Tangney's initial position is implausible because, if "supported by citation" is read to mean merely the mention of a drug's use in Drugdex, it would include the listings that are not supported by evidence. See infra Part II-B-1 (describing three uses of Dronabinol listed in Drugdex, that are also, per Drugdex, not supported by the evidence).

[7] The other listed therapeutic uses for Dronabinol are "AIDS - Loss of appetite," "Chemotherapy-induced nausea and vomiting; Prophylaxis," "Gilles de la Tourette's syndrome," "Loss of appetite, Cancer-related," "Multiple sclerosis - Spasticity," "Nausea and vomiting, Disease-related, treatment refractory," "Postoperative nausea and vomiting; Treatment and Prophylaxis," and "Pruritus, Cholestasis-associated, treatment refractory[.]" Admin. R. 0181-0186.

vomiting, Disease-related, treatment refractory" (the "Therapeutic Use"). Id. at 0181-0186. Drugdex states its recommendation for the Therapeutic Use as "Evidence favors efficacy[,]" in contrast to its recommendation for two other uses, which have a rated "Efficacy" of "inconclusive." See id. at 0181-0186. Drugdex classifies the "Strength of Evidence" for the Therapeutic Use as Category C, which includes "[e]xpert opinion or consensus, case reports, or case series," id. at 0018; this type of evidence contrasts with "randomized control trials," which would constitute a stronger category of evidentiary support, id.

The summary of the "Therapeutic Use" states: "Intractable nausea and vomiting related to metastatic cancer of the gastrointestinal mucosa resolved only after addition of [Dronabinol.]" Id. at 0185. Drugdex's recommendation for using Dronabinol for the Therapeutic Use is "Class IIB," meaning that the treatment "may be useful and is indicated in some, but not most, cases." Id. at 0009. The Therapeutic Use entry, and Drugdex's accompanying recommendation, are based on a single case study, to which the entry provides a citation. See id. at 0185 n.25.

2. Case Study

The underlying study ("Case Study") to which the Drugdex entry provides a citation was published in the Journal of Pain

and Symptom Management,[8] see id. at 0017, under a heading called "Palliative Care Rounds."[9] See Francisco Gonzalez-Rosales & Declan Walsh, Intractable Nausea and Vomiting Due to Gastrointestinal Mucosal Metastases Relieved by Tetrahydrocannabinol (Dronabinol) ("Case Study"), 14 J. of Pain & Symptom Manag. 311 (1997). The Case Study focuses on the treatment of a single patient (the "Patient"). It begins by summarizing existing research[10] and identifying its purpose, which is investigating "the use of Dronabinol as an antiemetic in patients with vomiting that is not chemotherapy related but is associated with advanced cancer." Id. at 311. The authors characterize the Patient's "main problem" as "intractable nausea and vomiting unresponsive to conventional antiemetics[.]" Id.

[8] The Journal focuses on "research and best practices related to the relief of illness burden among patients afflicted with serious or life-threatening illness." Journal of Pain and Symptom Management, http://www.jpsmjournal.com/content/aims. Its tagline is "[a]dvancing palliative care, hospice, and symptom research." Id.

[9] The aim of this section is "to provide case-based information relevant to the clinical practice of palliative care." Journal of Pain and Symptom Management, Guide for Authors, https://www.elsevier.com/journals/journal-of-pain-and-symptom-management/0885-3924/guide-for-authors.

[10] The Case Study notes that Dronabinol is currently "recommended . . . for chemotherapy induced nausea and vomiting when other antiemetic medication are not effective. . . . [and] for anorexia cachexia in [AIDS.]" Case Study 311. It also notes that there "is some information in the literature" about other uses, such as alleviating "nausea and vomiting related with anesthesia[.]" Id.

They posit that "the main cause of the nausea and vomiting was diffuse gastrointestinal mucosal tract metastases." Id. at 311-12. Administering Dronabinol worked like a charm for the Patient, eliminating his "pain, nausea, vomiting, [and] constipation[.]" Id. at 313.

But the authors are not sure why, or, more precisely, how, Dronabinol worked to relieve the Patient's symptoms. See id. ("The mechanism of the antiemetic effect of [Dronabinol] is unknown[.]"). Their best guess is that Dronabinol binds to the "opiate receptors in the forebrain[,]" which "inhibit . . . the vomiting center in the medulla[.]" Id. This would not have anything to do with the underlying cause of the nausea, which, they suspected, was cancer-related.[11] The authors conclude that "low doses of Dronabinol may be safe and effective when used in combination with other antiemetics for intractable cancer-related nausea and vomiting with no mechanical obstruction. Dronabinol should be considered a potentially useful agent in this setting." Id. at 314.

C. Prior Decisions

[11] The authors reiterate that there are many causes of nausea in cancer patients, see Case Study 313 ("Nausea and vomiting are among the 20 most frequent symptoms in advanced cancer. The etiology is multifactorial."), and suggest one in their case, see id. ("In this case, we believe that the main cause was diffuse metastatic disease in the gastrointestinal tract mucosa.").

With this statutory framework and factual background in mind, the Court next summarizes the reasoning of each of the decisions below.

1. Hearing Officer's Decision

The hearing officer issued a ruling finding that Medicare Part D covered Tangney's use of Dronabinol because the use was supported by a citation in Drugdex. See Admin. R. 0125-0133. He rejected the Secretary's narrow interpretation of the Drugdex listing, which is limited to cancer patients with treatment-resistant nausea, for two main reasons.

First, and most importantly, the expansive title of the Drugdex therapeutic use at issue here -- "nausea and vomiting, disease-related, treatment refractory" -- contrasted with the titles of other therapeutic uses, which were limited to specific diseases, such as "nausea and vominting, cancer-related, treatment refractory" and "chemotherapty-induced nausea and vomiting[.]" See id. at 0131-0132 (internal citations omitted). Thus, the plain meaning of the Drugdex entry supported the palliative use to treat Tangney's symptoms in this case: she too had "nausea and vomiting, disease-related, treatment refractory" and there was no reason, in the entry, to suspect that the treatment would not work to alleviate her symptoms, as well. See id. at 0132.

Second, the hearing officer considered Tangney's real-world history. See id. Specifically, he observed that Dronabinol had worked in treating her symptoms in the past, and that "without coverage of this drug, [Tangney] will either have to remain in the hospital indefinitely or possibly die." Id.

2. Appeals Council's Decision

The Council reached the opposite conclusion of the hearing officer: Tangney's use of Dronabinol was not supported by a citation in Drugdex. See id. at 0007-0023. It emphasized that Drugdex "is not written by a legislative body and [is] thus not structured with the expectations and assumptions that underlie statutory drafting." Id. at 0016. The Council proceeded to criticize the hearing officer's reliance on the title of the Therapeutic Use -- "Nausea and vomiting, Disease-related, treatment refractory," id. at 0181 -- because such titles in a compendia are merely "analogous to labels on file folders." Id. at 0016. Such labeling has very little probative value, the Council reasoned, because a broad-sounding title could reflect that "indications will be recommended based on citations as the [scientific] literature develops." Id. at 0019. (The Council's reasoning does not explain the variation among the titles identified by the hearing officer; the Council did not suggest why the other, more specific titles, lacked an expectation that the scientific literature would develop.)

Although it is without medical expertise, the Council also purported medically to evaluate the Case Study. The Council interpreted the Case Study very narrowly: because its authors did not know how Dronabinol worked,[12] there was no basis for concluding that the Case Study supported the use of Dronabinol to treat to other, non-identically-diagnosed patients. See id.

The Council put the most weight on the wording of the Case Study's conclusion, which, again, was that "low doses of Dronabinol may be safe and effective when used in combination with other antiemetics for intractable cancer-related nausea and vomiting with no mechanical obstruction." Id. at 0018 (quoting Case Study 314). Due to this "cancer-related nausea" limitation in its conclusion, the Council reasoned that using Dronabinol on patients with nausea that was not cancer related was not supported by the Drugdex entry's citation to this study. See id.

III. ANALYSIS

Having described the administrative agency's decisions and the underlying facts and compendium entry on which they were based, the Court now turns to its analysis of the parties' opposing motions. Although the Court holds that the Council's

[12] The Council did not discuss that, while admitting that "the mechanism . . . is unknown" the authors of the study did hypothesize that that Dronabinol binds to the "opiate receptors in the forebrain[,]" which "inhibit . . . the vomiting center in the medulla[.]" Case Study 313.

decision, and its implied definition of "supported by," is not entitled to deference under Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984) ("Chevron deference"), it does command respect pursuant to Skidmore v. Swift & Co., 323 U.S. 134 (1944) ("Skidmore deference"). Applying Skidmore deference to the substantive issue of whether Tangney's use of Dronabinol is "supported by" a citation in Drugdex, the Court concludes that the Council's reasoning is unpersuasive, and holds that Tangney's use of Dronabinol, because palliative, is supported by the citation in Drugdex to a case study of a patient with the same symptoms.

A. Standards of Review

The first issue is the appropriate standard of review. Here, this issue actually requires the analysis of two issues -- the appropriate deference to a factfinder, and to an expert agency -- which will be discussed in turn.

1. Questions of Fact, Questions of Law

The governing statute and caselaw are, at first glance, clear in defining how the Court ought review final decisions of the Secretary: such decisions will stand if supported by substantial evidence, so long as the proper legal standard was employed. See 42 U.S.C. § 405(g); Seavey v. Barnhart, 276 F.3d 1, 9 (1st Cir. 2001) (stating that the standard of review is "whether the final decision is supported by substantial evidence

and whether the correct legal standard was used") (internal citations omitted). Tangney agrees that this is the standard. See Pl.'s Reply 3.

This simple-sounding standard, however, encapsulates two different standards of review, for two different types of issues. The agency's findings of fact, "if supported by substantial evidence, shall be conclusive." Seavey, 276 F.3d at 10 (quoting 42 U.S.C. § 405(g)). This deference is justified, because the agency is the one on the ground, so to speak: "the responsibility for weighing conflicting evidence, where reasonable minds could differ as to the outcome, falls on the Commissioner and his designee[,] . . . [and] [i]t does not fall on the reviewing court." Id. There is no cause for deference if the issue is a legal one, however, because the Court is in as good of a position to interpret the law as anyone, thus de novo review of these issues, see id. at 9, also makes sense.[13]

So far, so good. But when the issue being raised is neither obviously a finding of fact, such as whether to believe one witness's testimony over another's, nor one of law, such as whether it is the applicant's burden to prove her eligibility or the Secretary's to prove her ineligibility, the rule statement above is of less help. These situtations involve so-called

[13] As will be discussed in the next section, an exception to this overarching principle applies where the agency possesses and brings to bear expertise regarding a particular issue.

mixed questions of law and fact, and they require the reviewing court to defer to the agency's determination to the extent that that determination involved fact-finding. As the First Circuit has explained:

> Many cases involve what courts term 'mixed' questions -- questions which, if they are to be properly resolved, necessitate combining factfinding with an elucidation of the applicable law. The standard of review applicable to mixed questions usually depends upon where they fall along the degree-of-deference continuum: the more fact-dominated the question, the more likely it is that the trier's resolution of it will be accepted unless shown to be clearly erroneous.

In re Extradition of Howard, 996 F.2d 1320, 1328 (1st Cir. 1993) (internal citations omitted).

The Court was unable to locate any published caselaw analyzing a challenge to the Secretary's determination analogous to the one here, where the facts are not in dispute, and the only question is whether the prescribed use is "supported by" a citation in a compendium entry.[14] The Council's analysis involved applying a statutory phrase ("supported by a citation")

[14] There are various district court cases interpreting the statutory phrase "supported by." See Diamond v. Sec'y of Health & Human Servs., No. 1:13 CV 2481, 2015 WL 367010, at *1 (N.D. Ohio Jan. 27, 2015); Broome v. Burwell, No. 6:14-CV-01248-MC, 2015 WL 1526532, at *1 (D. Or. Apr. 1, 2015); Nievod v. Sebellius, No. C 11-4134 SBA, 2013 WL 503089, at *1 (N.D. Cal. Feb. 8, 2013). In those cases, however, the claimaints did not argue that their prescribed uses were supported by a citation in the one of the compendia, but rather that such support was not a statutory requirement. Tangey does not advance this statutory interpretation. Instead, she argues that her use of Dronabinol is supported by a citation in Drugdex.

to undisputed facts (Tangney's medical records, and the relevant Drugdex entry). The issue is confusing.[15] Most telling is that the Council, like the Court, necessarily based its decision on a "cold administrative record," Seavey, 276 F.3d at 9. The Council, in its review, had to determine whether "the [hearing officer] disregarded Medicare law and rules relative to Part D coverage[.]" Admin. R. 0014.[16] In the securities enforcement context, the First Circuit has held that a lesser level of deference applies to agency decisions resulting from an appeals-council-type body's reversal of a hearing officer's determination:

---

[15] Indeed, the Secretary appears confused, as well. Compare Def.'s Mem. 12 (framing its determination that Tangney's use of Dronabinol is not supported by a citation in Drugdex as one of fact) with id. at 13-14 (arguing that its determination was a legal one involving its interpretation of the phrase "supported by citation[.]").

[16] This point is further supported by the Council's summation of its decision, which, while containing language nodding towards facts, reveals that it thought the reversible error was one of law. See Admin. R. 0015 ("[T]he Council finds reversible legal error in the [hearing officer's] decision, and finds that the decision is inconsistent with the preponderance of the evidence of record.") (emphasis supplied); id. at 0016 (stating that the hearing officer "misapprehended the nature and structure of the Drugdex compendium listings, sections, and the citations therein."). Again, in the Council's view, the true error in the hearing officer's decision was a legal interpretative one. See id. at 0016 ("As a result of the [hearing officer's] errors in interpreting the compendium, he erroneously gave weight to evidence not related to the issue of whether the drug Dronabinol is used for a medically accepted indication in this case.").

> When the [Securities and Exchange Commission] and the [hearing officer] reach different conclusions, the [hearing officer]'s findings and written decision are simply part of the record that the reviewing court must consider in determining whether the [Securities and Exchange Commission]'s decision is supported by substantial evidence. Because evidence supporting a conclusion may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the [appeals council]'s than when the [hearing officer] has reached the same conclusion, where the [Securities and Exchange Commission] has reached a conclusion opposite of that of the [hearing officer], our review is slightly less deferential than it would be otherwise[.]

Flannery v. S.E.C., 810 F.3d 1, 9 (1st Cir. 2015) (internal quotation marks and citations omitted).

Accordingly, the Court holds that the Council's ruling was, in the main, a ruling on matter of law,[17] and is entitled to little deference as such.

2. The Appropriate Level of Deference

[17] This legal ruling arguably sits in some tension with the Seventh Circuit's discussion of this same issue -- whether a patient's use of a given drug is "supported by" a citation in a compendia and thus covered by Part D -- albeit in the False Claims Act context. See United States v. King-Vassel, 728 F.3d 707, 717 (7th Cir. 2013) (treating the issue as one of fact). In King-Vassel, the Seventh Circuit emphasized the fact-specific nature of the inquiry, stating that "any given prescription could turn out to be unsupported [by a citation in Drugdex] for any number of reasons -- from the relatively simple to the dizzyingly complex." Id. There, however, the district court was serving its trial function, not reviewing an agency's action, and thus the discussion seems of limited relevance here. See id. (reversing district court's ruling that an expert was per se necessary to interpreting the compendia's listings and determining whether they supported a given prescription).

When reviewing an agency adjudication that involves matter of law, the Court's usual reviewing posture is de novo, as discussed above. The Secretary argues that, insofar as the Council's decision here interpreted a statutory phrase,[18] that interpretation is entitled to Chevron deference, Def.'s Mem. 11-12. Tangney disagrees. See Pl.'s Mem. 11-13; Pl.'s Reply 4-6. The Court mostly agrees with Tangney, but finds that Skidmore deference applies.

Whether the Council's interpretation of Part D's requirements deserves Chevron deference appears to be an open question in the First Circuit.[19] Chevron deference applies[20]

[18] The Secretary appears to argue that a press release stating that "supported by" is different than merely "listed in" constitutes an interpretation that is entitled to Chevron deference. See Def.'s Mem. 13-14 (citing Ctr. for Medicaid and State Operations, Medicaid Drug Rebate Program Release No. 141, For State Medicaid Directors: Compendia Clarification). As discussed above, the relevant inquiry is whether the interpretation had the force of law. This press release did not, and thus does not receive Chevron deference. It adds no value to the Secretary's argument and is omitted from the rest of the discussion.

[19] In Doe v. Leavitt, 552 F.3d 75 (1st Cir. 2009), the First Circuit confronted a situation somewhat analogous to the one before the Court. The court there explained that:

> the Secretary [of Health and Human Services] has not exercised this rulemaking authority to set forth his interpretation of the word 'investigation.' Instead, the Secretary's interpretation must be gleaned from (i) an agency manual, the NPDB Guidebook (the Guidebook), issued in September of 2001, and (ii) the Secretary's decision in this case. The appellant contends that these 'informal' interpretations do not

where the interpretation is "the type of legislative ruling that would naturally bind more than the parties to the ruling." United States v. Mead Corp., 533 U.S. 218, 232 (2001); see also id. at 233 (noting that the agency classification there did not qualify because it was "conclusive only as between itself and the importer to whom it was issued"); Patel v. Johnson, 2 F.Supp.3d 108, 120 (D. Mass. 2014) ("[T]he primary consideration governing the type of deference that ought apply is whether the interpretation was intended 'to carry the force of law,' and a major indicator of that intention is whether the decision was precedential and published.") (quoting River St. Donuts, LLC v. Napolitano, 558 F.3d 111, 115-16 (1st Cir. 2009)).

---

warrant deference under the familiar rubric of Chevron.

Id. at 79 (1st Cir. 2009). After noting that "the level of deference owing to informal agency interpretations is freighted with uncertainty[,]" the court there declined to decide the issue. Id. at 80 (citing Lisa Schultz Bressman, How Mead Has Muddled Judicial Review of Agency Action, 58 Vand. L. Rev. 1443, 1457–69 (2005)).

[20] Whether Chevron deference applies is an important issue. If it does, the Court would adopt the agency's interpretation of the law unless it was "procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." United States v. Mead Corp., 533 U.S. 218, 219 (2001) (internal footnote and citations omitted). This level of deference to agency decision-making strikes some scholars as undermining the judiciary's function as a check on executive power. See, e.g., Ronald A. Cass, Vive La Deference?: Rethinking the Balance Between Administrative and Judicial Discretion, 83 Geo. Wash. L. Rev. 1294 (2015).

Tangney correctly points out that the Council's decisions are, per the regulations promulgated by the agency itself, non-precedential. See Pl.'s Reply 5, citing 42 C.F.R. §§ 405.1048, 405.1130 ("The [Council's] decision is final and binding on all parties [to the action.]"). Thus the Court will not accord the Council's decision, and any statutory interpretation contained therein, Chevron deference. Compare Garcia-Quintero v. Gonzales, 455 F.3d 1006, 1012 (9th Cir. 2006) ("[B]ecause the [Board of Immigration Appeals'] decision was an unpublished disposition, issued by a single member of the [Board of Immigration Appeals], which does not bind third parties, we conclude that it does not carry the force of law."), abrogated on unrelated grounds by Medina-Nunez v. Lynch, 788 F.3d 1103, 1104 (9th Cir. 2015), with Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs., 545 U.S. 967, 980 (2005) (applying Chevron deference because of "provisions [that] give the [agency] the authority to promulgate binding legal rules") (emphasis supplied). This does not end the deference question, however.

3. Applying Skidmore Deference

The First Circuit has laid out a roadmap for how to proceed once a court determines that Chevron deference does not apply:

> [W]hen an agency speaks with something less than the force of law, its interpretations are entitled to deference only to the extent that those

> interpretations have the "power to persuade." [This is Skidmore deference.] That is the situation here. We must, therefore, dig deeper.
>
> To gauge persuasiveness, an inquiring court should look to a "mix of factors" that "either contributes to or detracts from the power of an agency's interpretation to persuade." Those factors include "the thoroughness evident in the agency's consideration, the validity of its reasoning, and the consistency of its interpretation with earlier and later pronouncements." "The most salient of the factors that inform an assessment of persuasiveness is the validity of the agency's reasoning."

Merrimon v. Unum Life Ins. Co. of Am., 758 F.3d 46, 55 (1st Cir. 2014), cert. denied, 135 S. Ct. 1182 (2015) (internal citations omitted). Those factors are "not exhaustive," and a court can consider, too, the formality of the agency process that produced the decision, as well as the extent to which it is based on the agency's expertise. See Doe v. Leavitt, 552 F.3d 75, 81 (1st Cir. 2009) (citing Kristin E. Hickman & Matthew D. Krueger, In Search of the Modern Skidmore Standard, 107 Colum. L. Rev. 1235, 1259 (2007)).

Four of the enumerated factors seem particularly relevant in the current case: (1) the agency's consistency, through the Council, in its restrictive interpretation of citations in approved compendia; (2) the formality of the process that led to the Council's decision; (3) the decision's non-precedential effect; and (4) the reasoning of the decision. These will be discussed in turn.

The Secretary highlights that the Council has been consistent in its application of "supported by," citing to several prior Council cases with holdings consistent with its position here. See Def.'s Mem. 15-17. The hearing officer himself was aware of this consistency -- noting that the Council "has found in similar cases that the therapeutic use headings in [the relevant compendium] should not be read expansively, but rather strictly," Admin. R. 6 -- but refused to follow the Council's prior rulings because they were non-precedential, see id. at 7. Tangney does not appear to dispute that the Council has been consistent in its restrictive definition of "supported by." This consistency favors deferring to the agency's interpretation.

The formality of the process that produced the Council's decision also nudges this Court towards deferring: Tangney was present and represented by counsel at each stage of the decision-making process, and the procedures were spelled out in advance. See Doe, 552 F.3d at 81 (stating that "[g]reater weight ordinarily is due to interpretations that result from a structured interpretive process as opposed to a catch-as-catch-can interpretive process."). On the other hand, though, the Council's decision was not precedential and thus not analogous to a proffered rule to be applied by all future hearing officers. This counsels against strong deference, see id.

("[G]reater deference is due to an interpretation that 'is not merely ad hoc but is applicable to all cases.'") (internal citation omitted), although it certainly does not suggest the Court ought abandon all deference, see Patel, 2 F.Supp.3d at 121 ("[W]hile this interpretation lacks the force of law, it was not a mere casual construction, but rather was the product of a multilayered intra-agency appellate process involving relatively formal procedures.") (internal citation omitted).

The final and "most salient" of the factors is the persuasiveness of the agency's reasoning. Merrimon, 758 F.3d at 55. "This inquiry does not focus on the [persuasiveness of the] interpretation per se but, rather, on whether the agency has consulted appropriate sources, employed sensible heuristic tools, and adequately substantiated its ultimate conclusion." Doe, 552 F.3d at 82. This means "something more" than deferring "only when an inquiring court is itself persuaded that the agency got it right." Id. at 81.

Here, the Council did consult "appropriate sources," id. at 82, discussing the Drugdex entry and the underlying Case Study, along with referencing various previous Council decisions, see Admin. R. 0015-0022. It also utilized some "heuristic devices," Doe, 552 F.3d at 82, while explicitly rejecting others. Specifically, the Council repudiated the hearing officer's use of a traditional statutory interpretation

device[21] because Drugdex, it said, is not legislation, and should not be interpreted as such. See Admin. R. 0016-0018. Instead of according much weight to the title of the Case Study, the Council reasoned that, because the compendia are made to "provide access to the [medical/scientific] research and the scientific evidence it contains[,]" determining what uses its citations support should be done by evaluating the underlying studies included therein. Id. at 0017-0018.

The Council's analysis of the Case Study, however, did not "adequately substantiate[] its ultimate conclusion." Doe, 552 F.3d at 82. The Council observed that, as a case study, it constituted "the lowest category for strength of evidence." Id. at 18. It also noted that the Case Study did not definitively identify how or why Drobabinol works. Id. Based on these factors, the Council determined that the listing ought be read very narrowly.[22] Id.

[21] See supra Part II-C-1 (describing hearing officer's comparision of the differences between titles of Drugdex Therapeutic Uses).

[22] Taking a step back, the Court observes that the regulatory scheme here forced Tangney into a Kafka-esque situation: trying to convince the Council that Tangney's use of Dronabinol was supported by a case study of a single patient, when, in fact, Tangney's record here itself constitutes a case study, with her having taken Dronabinol to near miraculous effect for three consecutive years before switching to Part D and being denied coverage.

While this interpretation is internally consistent, it fails completely to engage with Tangney's argument, which is essentially that it does not matter how Dronabinol works, because it is merely treating symptoms, not the underlying disease.[23] The Secretary allows that "the palliative use of Dronabinol for nausea related to stomach cancer, a use likely approved for that patient after consideration of the specific dangers involved[,]" would be supported by the Drugdex citation. Def.'s Mem. 15. A few sentences in its memorandum later, the Secretary appears to go further, noting that the Drugdex citation, "read broadly," "is . . . for otherwise untreatable nausea in patients with a cancer diagnosis." Id. The Council's, and the Secretary's, application of "supported by" fails to explain its choice of scope. Tangney's interpretation -- that, since she is receiving palliative care, like the patient in the underlying case study, the similarity of their symptoms should control -- in contrast, is clear in why it governs in this particular case.

Another way of stating this is that there is a level-of-generality problem. While Tangney has an explanation for her level of generality, the Secretary does not. The Council (and, now, the Secretary) frames Tangney's use of Dronabinol as

[23] This interpretation is supported by the journal in which the case study was published. See supra notes 8 and 9 (describing focus on palliative care research).

treating her nausea that is caused by her particular diseases/conditions. See Admin. R. 0016. Only because of this framing is the absence in both the Drugdex entry and the underlying case study to "nausea and vomiting secondary to severe gastroparesis and intestinal motility disorder" evidence that the citation does not support her use. Id. Conversely, Tangney argues that her Dronabinol prescription merely treats her symptom of treatment-resistent nausea, regardless of the underlying cause, because she is receiving palliative care. See Pl.'s Reply 6. Thus, "[w]hile a curative drug may logically be limited to a specific diagnosis, a drug [like Dronabinol] that is used to treat symptoms should be more logically linked to the specific symptoms." Id. at 6-7.

This failure to explain, coupled with the facts of this particular case, and, as Tangney points out, the favorable-to-claimants tradition in ambiguous Social Security cases, Pl.'s Reply 7; see also, e.g., McCuin v. Sec'y of Health & Human Servs., 817 F.2d 161, 174 (1st Cir. 1987) ("[T]he Social Security Act . . . is a remedial statute, to be broadly construed and liberally applied in favor of beneficiaries.") (internal citation omitted), compels the Court to adopt her reading of the statutory scheme[24] and underlying Case Study.

[24] Tangney does not advance the statutory interpretation adopted by the Southern District of New York in 2011,

IV. CONCLUSION

The Court vacates the decision of the Council, and thus DENIES the Secretary's motion for an order affirming the decision of the Secretary, ECF No. 20, and GRANTS Tangney's motion to reverse the Secretary's decision, ECF No. 17.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE

---

recognizing that, while favorable to claimants such as herself, it represents a minority position. See Pl.'s Mem. 9 ("Unlike most cases which have challenged the Secretary's denial of coverage for an off label use under Medicare Part D, [Tangney] does not challenge the requirement [that the prescribed use be a medically accepted indication.]"). The Southern District, in Layzer v. Leavitt, 770 F. Supp. 2d 579 (S.D.N.Y. 2011), construed the statute's inclusion of coverage for prescriptions "for a medically accepted indication," as inclusive, not as exhaustive, meaning that it was not per se required for a prescription to be covered under the statute. Id. at 583-87.